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UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF NEW YORK

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KERYX BIOPHARMACEUTICALS, INC.,	X	
	X	
Plaintiff,	X	ECF CASE
	X	
- against -	X	07 Civ. 10376 (CSH)
	X	
PANION & BF BIOTECH, INC.,	X	
	X	
Defendant.	X	
-----	X	

**MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

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PRELIMINARY STATEMENT

This action arises from defendant's blatant breaches of the of the parties' License Agreement, dated as of November 7, 2005, pursuant to which Panion granted Keryx an exclusive right to develop and commercialize a chemical compound, ferric citrate, as a pharmaceutical product for the treatment of kidney disease.

The License Agreement is an important corporate asset of Keryx, and Keryx has devoted substantial corporate resources and incurred substantial expense in performing development work for the ferric citrate product (the "Licensed Product"). As a result of Keryx's investments in the Licensed Product and its reputation in the pharmaceutical community for the development of early stage pharmaceutical products, Keryx was able to enter into an exclusive sublicense for the Licensed Product for Japan (the "Japanese Sublicense") with Japan Tobacco, Inc. and Torii Pharmaceutical Co. Ltd. (collectively, "Japan Tobacco"). Pursuant to the Japanese Sublicense, Japan Tobacco agreed to pay Keryx an up-front licensing fee of \$12 million plus future milestone payments and royalties. Panion has no right under the License Agreement to share in this licensing fee.

Apparently upset with the deal it struck with Keryx two years earlier, Panion has engaged in a campaign to extort money from Keryx and renegotiate the License Agreement by (i) threatening to terminate the License Agreement without basis and in breach of the express 90-day cure provision in Section 12.3 of the Agreement, (ii) threatening to commence (and later commencing) proceedings against outside contractors working with Keryx to perform vital development work on the Licensed Product pursuant to its express right under Section 3.1 of the Agreement to "develop, have developed, make [and] have made" the Licensed Product, and (iii) refusing to consult in good faith with Keryx and its sublicensee Japan Tobacco concerning the prosecution in Japan of the licensed patent rights, including by refusing to request a routine, but critical extension of the deadline for responding to an Office Action from the Japanese patent office initially rejecting the patent application, after having previously agreed to seek the

extension and failed timely to advise Keryx of the Office Action, in breach of the express requirements of Section 8.1.1 of the Agreement and its duty of good faith and fair dealing requiring Panion to “regularly consult with Licensee and keep Licensee advised of the status of all patent applications . . . [and] provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence.”

Panion’s actions directly contravene Keryx’s bargained-for contractual rights and, if permitted to continue, will cause Keryx irreparable harm. Absent immediate injunctive relief, irreplaceable patent rights in Japan may be lost, the substantial value of Keryx’s licensed rights will be impaired, development work critical to the eventual success of the Product as a commercial drug will be blocked or delayed, and Keryx’s reputation in the pharmaceutical community will be undermined. Under the circumstances, the right to injunctive relief is clear.

Accordingly, Keryx’s motion for an order preliminarily enjoining Panion (i) from serving a notice of termination under the License Agreement prior to January 30, 2008, (ii) from interfering with Keryx’s rights under the License Agreement to develop the licensed Product, and (iii) from failing to consult and notify Keryx in good faith concerning prosecution of licensed patent applications, should be granted.

STATEMENT OF FACTS¹

Keryx is a publicly traded pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious conditions, including diabetes, cancer, and renal (kidney) disease. (Weiss Decl. ¶ 2.) Under an exclusive patent license (the “License Agreement”) from Panion & BF

¹ The relevant facts are set forth in the declarations of William Bennett, Beth Levine and Eiichi Arai, dated November 20, 2007, and the declarations of Michael S. Weiss and Gregg L. Weiner, dated November 19, 2007 (both attached to the declaration of Gregg L. Weiner, dated November 20, 2007).

Biotech, Inc. (“Panion”), dated November 7, 2005, Keryx is developing a chemical compound, ferric citrate, as a pharmaceutical for treatment of disease. (Id. ¶ 3; Exh. 1.) Under the License Agreement, Keryx’s exclusive rights to develop and commercialize ferric citrate extend throughout most of the world, including the United States, Japan, and Canada, and include the right to grant sublicenses to third parties. (Weiss Decl. ¶ 3; Exh. 1.)

The License Agreement is an important corporate asset of Keryx, and Keryx has devoted substantial corporate resources and incurred substantial expenses in performing two categories of development work for ferric citrate. (Id. ¶ 4; Bennet Decl. ¶ 8) The first category includes work undertaken to generate information that is needed for successful commercialization of ferric citrate as a pharmaceutical. In developing ferric citrate as a pharmaceutical product, Keryx works with a number of outside contractors, including BRI Pharmaceutical Research, Inc. (“BRI”) in Vancouver, Canada, which was introduced to Keryx by Panion. BRI, in turn, introduced Keryx to BioVectra DCL (“BioVectra”) in Prince Edward Island, Canada, and through BioVectra to the PharmPro Services division of Fluid Air, Inc. (“PharmPro”), which is located in Aurora, IL among other places. (Bennet Decl. ¶¶ 7, 9.) All the activities currently being performed for Keryx by BRI, BioVectra and PharmPro fall into the first category of information-gathering development work that provides Keryx with information needed for drug development but does not result in Keryx being supplied with ferric citrate Drug Substance (API) or Drug Product. (Id. ¶ 10.) Section 3.1 of the License Agreement expressly authorizes Keryx to use Panion-owned technology (“Licensor Know-How”) to “develop, have developed, make [and] have made” the licensed product. (Weiss Decl. Exh. 1.) Panion has not accused Keryx of breaching the License Agreement by performing this first category of information-generating work. (Id. ¶ 5.)

The second category of development work for ferric citrate concerns work that involves providing a supply of ferric citrate to Keryx, for use in toxicology testing and clinical trials. The License Agreement provides in Section 7.7 that during an exclusive supply period (which has not

yet expired), and subject to certain conditions, Keryx and its sublicensees shall obtain their supply of the Clinical Supplies exclusively from Panion, subject to certain price competition provisions. (Id. ¶ 6; Exh. 1.)

As early as July 2006, Keryx advised Panion that it urgently needed 100 kg of ferric citrate Drug Substance (API) for use in toxicology studies. (Bennet Decl. ¶ 12.) In response, Panion introduced Keryx to BRI (Panion's previous contractor) for the purposes of organizing supply but then declined to participate in any planning, saying that it simply wished to be kept informed. Keryx kept Panion informed of its development program by emails and progress reports, and invited Panion to meetings with BRI, which Panion declined to attend on the grounds that "Panion is a small company with limited budget and resources." (Id. ¶ 12.; Exh. 3.) Keryx repeatedly informed Panion of its purchase of API from Biovectra, and even offered to increase its order to accommodate Panion's need for supply. (Id. ¶¶ 15-17)

On September 18, 2007, Keryx advised Panion that it was about to grant an exclusive sublicense for Japan (the "Japanese Sublicense") to Japan Tobacco, Inc. and Torii Pharmaceutical Co. Ltd. (collectively, "Japan Tobacco") and asked Panion to sign a consent form for the comfort and assurance of the sublicensees (even though Panion's consent was not contractually required). (Weiss Decl. ¶ 7.) Panion declined to sign the consent form, and the Japanese Sublicense was nevertheless executed, with effect from September 26, 2007, for an upfront licensing fee of \$12 million plus future milestone payments and royalties, collectively estimated to be worth \$100 million. (Id. ¶ 7.)

On September 22, 2007, after learning about the Japanese Sublicense, Panion for the first time accused Keryx of having breached the License Agreement by ordering certain supplies of ferric citrate in 2006 from BioVectra. (Id. ¶ 8.) On October 31, 2007, Panion's counsel, Albert Wai-Kit Chan, emailed to Keryx a notice contending that Keryx's orders in 2006 constituted "a material breach" of the License Agreement that "has not been cured for more than ninety days" and threatening to "take appropriate actions to nullify th[e] agreement." (Id. ¶ 8; Exh. 2.)

Section 12.3 of the License Agreement permits termination for cause only if Keryx fails to cure a material breach within ninety days after Panion has given written notice of default. (Id. Exh. 1.) Panion has not retracted its false claim that the ninety-day cure period has expired or its threat to terminate the License Agreement. (Id. ¶ 8.)

On or about November 7, 8 and 9, 2007, Panion's counsel contacted Keryx's contractors, BRI, BioVectra and PharmPro, demanding that they cease the work they are performing for Keryx, on the grounds that they are using Panion-owned technology, and threatening to commence proceedings against them unless they agreed to do so. (Id. 9; Exhs. 3-5) That work includes the information-gathering development work that Keryx is authorized under the License Agreement to do or have done by its contractors. (Id. ¶ 9.)

On November 12, 2007, counsel for Keryx wrote to Panion's counsel, explaining that Keryx believed it had not breached the License Agreement, giving an assurance that during the Exclusive Supply Period, Keryx would submit future orders for Clinical Supplies of ferric citrate to Panion in accordance with Section 7.7(b) of the License Agreement, and asking Panion to confirm that this sufficed to cure the alleged breach or else to state what else was needed to cure. Keryx also asked Panion to cease and desist from threatening Keryx's contractors. (Id. ¶ 10.)

Panion did not reply to the November 12, 2007 letter, but instead repeated and escalated its threats and demands to BRI, BioVectra and PharmPro, and on November 15, 2007 filed a Summons with Notice in New York Supreme Court, Queens County, purporting to assert claims against BRI and seeking to enjoin BRI from continuing its contract work for Keryx. (Weiner 11/19 Decl. Exh. 6.) It has since filed a similar summons with Notice against Biovectra. (Weiner 11/20 Decl. Exh. C)

Panion also is refusing to consult in good faith with Keryx and its sublicensee concerning the prosecution in Japan of the patent rights that Panion licensed to Keryx and that Keryx has in turn sublicensed to Japan Tobacco. (Weiss Decl. ¶ 12.) Section 8.1.1 of the License Agreement provides that Panion shall "use reasonable efforts to prosecute the patent applications" that are

included in the license and shall “regularly consult with Licensee and shall keep Licensee advised of the status of all patents and patent applications relating to the Patent Rights . . . [and] shall provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence.” (Id. 12; Id. Exh. 1.) The Japanese patent office issued an Office Action on August 28, 2007, which rejected the patent application but permitted a response to be submitted by November 28, 2007, unless that deadline is extended. (Levine Decl. ¶ 3.) Panion failed to advise Keryx of the Notice until October 1st. (Id. ¶ 8.) After finally learning of the Office Action, Keryx requested that Japan Tobacco’s patent counsel meet with Panion’s counsel. Japan Tobacco’s patent counsel was initially permitted to meet with Panion’s Japanese patent counsel to discuss how to respond to the Office Action issued by the Japanese Patent Office. (Id. ¶ 12.) Panion, however, thereafter instructed its Japanese patent counsel not to communicate with Japan Tobacco’s counsel. (Weiss Decl. ¶ 12; Exh. 2.)

In addition, having agreed on October 24, 2007 to request a three-month extension of the deadline for responding to the Office Action, which Japanese counsel believes is important to procuring a patent in Japan, Panion switched course and informed Keryx that it would not seek the extension “based on the unresolved issues between Keryx and Panion.” (Weiss Decl. ¶ 12; Weiss Decl. Exh. 6.) An extension is necessary because Japan Tobacco has located over 3,000 articles which need to be analyzed in support of the patent and there is not sufficient time – because of Panion’s failure to notify Keryx of the Office Action until more than a month after it was issued – to properly address the issues raised by the Patent Office. (Levine Decl. ¶ 19.) Requests for extensions of 3 months or less are always granted by the Japanese Patent Office upon the payment of a fee of less than \$60. (Arai Decl. ¶ 3.) Panion’s actions and failures to act threaten to cause Keryx irreparable harm.

ARGUMENT

KERYX IS ENTITLED TO A PRELIMINARY INJUNCTION

In order to obtain preliminary injunctive relief, the Plaintiff must show (1) “irreparable harm in the absence of the injunction” and (2) either (a) a likelihood of success on the merits or (b) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in the movant’s favor.” Bose Corp. v. Silonsonnic Corp., 413 F. Supp. 2d 339, 341 (S.D.N.Y. 2006) (citation omitted).

“[A] showing of probable irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction[.]” Reuters Ltd. v. United Press Intern., Inc., 903 F.2d 904, 907 (2d Cir. 1990) (citations omitted). To satisfy the threshold requirement of irreparable harm or injury, a movant need not demonstrate that the harm will certainly occur, but merely that such irreparable injury is “probable” or “likely.” See Wenner Media LLC v. Northern & Shell North America Ltd., No. 05 Civ. 1286, 2005 WL 323727, at *3 (citations omitted).

A. Keryx Will Be Irreparably Harmed If a Preliminary Injunction Is Not Issued

The irreparable harm faced by Keryx absent an injunction is plain. The License Agreement is an enormously valuable agreement to Keryx and a key part of its business. The improper early termination of the Agreement by Panion or interference by Panion with Keryx’s rights under the Agreement would halt development of the product, undermine Keryx’s reputation in the Japanese market and elsewhere, and expose Keryx to vast damages which would not be readily ascertainable or likely to be recovered from a small company such as Panion.

First, Panion’s failure to cooperate in good faith with Keryx concerning prosecution of licensed patent applications, including its failure to timely notify Keryx of the Office Action issued by the Japanese Patent Office in August 2007 and its refusal thereafter to seek a

previously agreed three-month extension for responding to the Notice, is an egregious breach of the License Agreement and threatens substantial irreparable harm to Keryx.

Keryx urgently needs Panion to comply with its duty under the License Agreement to cooperate with Keryx and its sublicensee in prosecuting the Japanese patent application. Successful prosecution of the Japanese patent application is critical to commercial development under the Japanese Sublicense, yet Panion failed to timely notify Keryx of the Notice and, according to Japan Tobacco, there is not sufficient time to gather and analyze all of the materials necessary for submitting a proper response to the Notice. (Levine Decl. ¶ 21.) The failure to obtain the Japanese patent will destroy the value of the \$100 million Japanese Sublicense and damage Keryx's reputation in the pharmaceutical community, upon which its entire business depends. Such harm would not be capable of being remedied by a judgment for money damages and manifestly constitutes irreparable harm. Towers Financial Corp. v. Dun & Bradstreet, Inc., 803 F. Supp. 820, 823 (S.D.N.Y. 1992) (finding irreparable harm where injury to the movant's "reputation in the business community" is "both imminent and 'incapable of being fully remedied by money damages'") (citing Reuters, 903 F.2d at 907). See also Danielson v. Local 275, Laborers Intern. Union of North America, AFL-CIO, 479 F.2d 1033, 1037 (2d Cir. 1973) (it is long-established that "[i]rreparable injury is suffered where monetary damages are difficult to ascertain or are inadequate").

Panion's interference with Keryx's activities related to the development of the Product under the License Agreement similarly exposes Keryx to an improper risk of irreparable injury. (Bennet Decl. ¶ 11.) Panion has repeatedly demanded that Keryx's contractors stop all work in conjunction with development of the Product, and in the last week, it has sued two of these contractors, seeking to block the work they are undertaking at Keryx's direction to develop the Product. Panion's conduct is clearly in violation of Keryx's broad development rights under the License Agreement, and also constitutes tortious interference with Keryx's existing and prospective business relations. "Such interference with an ongoing business, particularly one

involving a unique product and an exclusive licensing and distribution arrangement, risks irreparable injury and is enjoinable. . . .” U.S. Ice Cream Corp. v. Carvel Corp., 136 A.D.2d 626, 628, 523 N.Y.S.2d 869, 871 (2d Dep’t 1988) (citations omitted). See also Johnson Controls, Inc. v. A.P.T. Critical Systems, Inc., 323 F. Supp. 2d 525, 530 (S.D.N.Y. 2004) *aff’d* 408 F.3d 112 (2d Cir. 2005) (finding irreparable harm where defendants are alleged to have tortiously interfered with plaintiff’s business relations by luring away clients).

Panion’s tortious conduct would inevitably delay the launch of the Product, undermining Keryx’s reputation as a leader in the development and commercialization of medically important pharmaceutical products. (Bennet Decl. ¶ 11.) Moreover, delay in launching the drug will cause Keryx to lose ground in the race against competing companies to bring the drug to market; and once lost, that lead time can never be recovered. Such a threat of loss of market share, like a loss of goodwill, is often immeasurable and thus constitutes irreparable injury. “A loss of market share...is difficult to quantify and represents the loss of an opportunity which may not be quickly or easily regained, and thus may be considered irreparable.” Freedom Holdings, Inc. v. Spitzer, 447 F. Supp. 2d 230, 262-63 (S.D.N.Y. 2004) (when absent an injunction a party will be prevented “from entering or gaining any foothold in the...market,” such injury is irreparable); Reuters, 903 F.2d at 908 (“even a speculative loss may cause immediate irreparable harm”).

Finally, a premature notice terminating the License Agreement -- and purporting to cut off Keryx’s opportunity to cure any alleged breach -- would cast a cloud over the Japanese Sublicense, causing severe and irreparable injury to Keryx and its public stockholders, including by delaying the development work needed to obtain regulatory approval for ferric citrate in Japan and by causing reputational injury to Keryx in Japan. Reputational harm and loss of goodwill as is threatened here has been found to be irreparable. See, e.g., Jacobson & Co. v. Armstrong Cork Co., 548 F.2d 438, 445 (2d Cir. 1977) (“We agree that Jacobson presented ample evidence to show a threatened loss of good will and customers, both present and potential, neither of which could be rectified by monetary damages.”); Vestron, Inc. v. National Geographic Soc., 750 F.

Supp. 586, 591 (S.D.N.Y. 1990) (“Vestron is committed to its subdistributors to supply them with the Society’s documentaries along with a variety of other titles. Failure to do so will result in litigation with the subdistributors, incalculable loss of revenues on other titles if their distribution is affected, and diminution of good will.”).

In short, Keryx faces substantial irreparable injury in the absence of the requested preliminary injunctive relief.

B. Keryx is Likely to Succeed on the Merits of Its Claims

A likelihood of success on the merits exists when there is a showing “that the probability of ... prevailing is better than fifty percent.” Eng v. Smith, 849 F.2d 80, 82 (2d Cir. 1988) (citation omitted). See also Varsames v. Palazzolo, 96 F. Supp. 2d 361, 366 (S.D.N.Y. 2000) (“In general, a movant proceeding on the basis of likelihood of success need only show that the probability of prevailing is greater than fifty percent.”); Reynolds v. Giuliani, 35 F. Supp. 2d 331, 339 (S.D.N.Y. 1999) (same).

Keryx has more than satisfied this standard.

1. Keryx Will Succeed On Its Claim that Panion Has Breached Its Obligations Under Section 8.1.1 of the License Agreement

Section 8.1.1 of the License of the License Agreement provides that Panion shall “use reasonable efforts to prosecute the patent applications” that are included in the license and shall “regularly consult with Licensee and shall keep Licensee advised of the status of all patents and patent applications relating to the Patent Rights . . . [and] shall provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence and submit to Licensor any proposed response thereto.” (Weiss Decl. Exh.1 (emphasis added)) This provision requires Panion to consult in good faith with Keryx concerning prosecution of the patent in Japan. See SVS, Inc. v. Rabbit Ears Productions, Inc., No. 91 Civ. 6632 1992 WL 91183, at *12 (S.D.N.Y. Dec. 12, 1991) (“Under New York law,

every contract contains an implied covenant of good faith and fair dealing.”) (citing Carvel Corp. v. Diversified Mgmt. Group, 930 F.2d 228, 230 (2d Cir. 1991)). In violation of this provision, Panion is refusing to consult in good faith with Keryx and its sublicensee concerning the prosecution in Japan of the patent rights that Panion licensed to Keryx and that Keryx has in turn sublicensed to Japan Tobacco. Panion’s breach of this provision could not be more clear.

As explained in the Levine Declaration, on August 28, 2007, the Japanese Patent office issued a Notice of Office Action with respect to the proposed patent in Japan, rejecting the proposed patent. A response to the Notice of Office Action is due on November 28, 2007, unless that deadline is extended. Panion did not notify Keryx of this action despite repeated requests for updated patent dockets, in violation of its obligations under Section 8.1.1. (Levin Decl. ¶ 4, 6.) Instead, Keryx was first notified of the office action by e-mail on October 1, 2007, and an English translation was not provided until October 10th. (Id. ¶ 7, 8.)

Moreover, while Japanese patent counsel initially were allowed to meet and Panion’s patent counsel thereafter agreed to the suggestion of Japan Tobacco’s counsel that the parties seek a routine three month extension of the time to respond to the Japanese patent office to allow sufficient time for a response to be prepared, Panion quickly did an about-face – blatantly asserting that it would not seek the extension “based on the unresolved issues between Keryx and Panion” and instructing its Japanese patent counsel not to communicate with Japan Tobacco’s counsel. (Weiss Decl. Exh. 6.) Panion’s conduct amounts to a plain breach of its express and implied obligations under the parties’ contract. See Orange County Choppers, Inc. v. Olaes Enterprises, Inc., 497 F. Supp. 2d 541, 559 (S.D.N.Y. 2007) (withholding notice in order to coerce concessions under agreement violated duty to “use reasonable effort to notify [other party] in writing”); Edrei v. Copenhagen Handelsbank A/S, No. 91 Civ. 1860, 1991 WL 64201, at *8 (S.D.N.Y. April 18, 1991) (holding that if defendant negotiated in bad faith, it breached contractual best efforts obligation as well as implied commitment to deal with plaintiff in good

faith). Plainly, Keryx is likely to succeed on the merits of claim that Panion breached Section 8.1.1 of the License Agreement.

2. Keryx Will Succeed On Its Claim That Panion Has Improperly Interfered With Keryx's Licensed Activities

Section 3.1 of the License Agreement, expressly permits Keryx to use Panion-owned technology ("Licensor Know-How") "to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export the Product . . ." (emphasis added). This broad grant of license rights necessarily includes work undertaken to generate information that is needed for successful commercialization of ferric citrate as a pharmaceutical product. These information-generating development activities do not result in Keryx being supplied with ferric citrate (Bennet Decl. ¶ 10), and therefore the requirement under Section 7.7 that Keryx obtain its supply of ferric citrate from Panion does not apply. See, e.g., Topps Co. v. Cadbury Stani S.A.I.C., 454 F. Supp. 2d 89, 104 (S.D.N.Y. 2006) (adopting the more inclusive interpretation of a grant in a license that is defined by the parties using "broad and expansive language").

Keryx has contracted with BRI, BioVectra and PharmPro to assist with this development work. (Bennet Decl. ¶ 7.) Panion's repeated and ongoing interference with the work being done by Keryx's contractors – on the false basis that they are misusing "Panion-owned technology" – plainly breaches Keryx's broad rights under Section 3.1 of the License Agreement to develop the Product using "Licensor Know-How," and will constitute tortious interference with Keryx's existing business relations unless enjoined.

3. Keryx Will Succeed On Its Claim For a Declaration That Panion May Not Serve a Notice of Termination Before January 30, 2008

Section 12.3 of the Agreement states, in pertinent part:

Licensor may terminate this Agreement in its entirety for cause at any time upon at least ninety (90) days prior written notice to Licensee upon the occurrence of any of the following.

(a) upon or after the breach of any material provision of this Agreement by Licensee if such breach is not cured within ninety (90) days after Licensor gives Licensee written notice thereof . . .

(Weiss Decl. Exh. 1.)

The notice provision of the Agreement provides as follows:

Any notices required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or if mailed by registered or certified mail (return receipt requested), postage prepaid, or by telex or facsimile or e-mail promptly confirmed by first class mail.

(*Id.* at § 22.)

It was not until October 31, 2007 that Panion sent Keryx a notice in conformity with Section 12.3 contending that Keryx's orders in 2006 constituted "a material breach" of the License Agreement.² Accordingly, under the plain and unambiguous provision of the Agreement, Keryx has until ninety days from October 31, 2007 – i.e., January 29, 2008 – to cure the alleged breach. Under New York law, which governs the Agreement, Keryx's plain right to a ninety-day cure period must be enforced as written. It is black-letter law that "when parties set down their agreement in a clear, complete document, their writing should as a rule be enforced according to its terms." W.W.W. Assocs., Inc. v. Giancontieri, 77 N.Y.2d 157, 162, 565

² Panion's earlier complaints in late September and October 2007 do not satisfy the notice requirement as they did not allege a material breach of the Agreement or conform to the notice requirement for confirmation of emailed notices "promptly by first class mail." See Lurzer GMBG v. Am. Showcase, Inc., 75 F. Supp. 2d 98, 102 (S.D.N.Y. 1998) ("when a party seeks the draconian remedy of forfeiture based on another party's failure to respond to a notice of default, the notice in question will be scrutinized carefully and any inadequacy, no matter how trivial, will defeat the claim"), *aff'd*, 201 F.3d 431 (2d Cir. 1999); Luxottica Group S.p.A. v. Bausch & Lomb, Inc., 160 F. Supp. 2d 545, 550 (S.D.N.Y. 2001) (same).

N.Y.S.2d 440, 443 (1990). See also SVS, Inc. v. Rabbit Ears Productions, Inc., 1992 WL 91183 at *10 (S.D.N.Y. 1992) (“Where the party asserting nonperformance does not give the defaulting party a chance to cure, the party asserting nonperformance cannot terminate the agreement.”). Accordingly, Keryx is likely to succeed on its claim that it has until January 29, 2008 to cure the alleged breach asserted by Panion.

C. Alternatively, There Are Sufficiently Serious Questions Going to the Merits to Make Them a Fair Ground for Litigation and the Balance of Hardships Tips Decidedly in Favor of Keryx

Even were the Court to find that the “likelihood of success on the merits” prong had not been met, here there are sufficiently serious questions going to the merits to make them a fair ground for litigation, and the balance of hardships tips decidedly toward Keryx.

1. Keryx’s Claims More Than Satisfy The Serious Questions Standard

Sufficiently serious questions going to the merits exist whenever there are fair grounds for litigating the dispute. See, e.g., Able v. U.S., 44 F.3d 128, 130-31 (2d Cir. 1995) (“This second ‘serious questions’ prong is also frequently termed the ‘fair ground for litigation’ standard.”); see also GFC Financial Corp. v. GFC Capital Resources Group, Inc., No. 93 Civ. 8001, 1994 WL 30432, at *2 n2 (S.D.N.Y. Feb. 2, 1994) (“The plaintiff...may obtain an injunction merely by showing that there are fair grounds for litigation and a balance of hardships tipping in his favor.”).

Keryx undeniably has presented a “fair ground for litigation.” See supra at 10-13; Koylum, Inc. v. Peksen Realty Corp., 272 F.3d 138, 143 (2d Cir. 2001) (affirming district court’s grant of preliminary injunction after district court adopted magistrate judge’s report in its entirety, and noting that “[t]he Magistrate Judge...found serious questions as to the propriety of the termination, first because these purported grounds were arguably not breaches supporting

termination and, in any event, Peksen had not given notice of these grounds in any of the termination notices as required by the PMPA.”).

2. The Balance of Hardships Tips Decidely In Keryx’s Favor

“To establish that the balance of hardships tips in their favor, the plaintiffs must demonstrate that the harm they would suffer absent the relief sought is substantially greater than the harm the defendants would suffer if the injunction were granted.” Greylock Global Opportunity Master Fund Ltd. v. Province of Mendoza, No. 04 Civ. 7643 HB 2004 WL 2290900, at *4 (S.D.N.Y. Oct. 12, 2004) (citation omitted). When public interests are implicated, however, a court should factor them in as well. Id. See also Carey v. Klutznick, 637 F.2d 834, 839 (2d Cir. 1980) (“[T]he public interest has always been a factor to be considered in the granting of a preliminary injunction.”).

The harm to Keryx absent injunctive relief would be vast and irreparable. See supra at pp. 7-10. The public would be harmed as well by the absence of injunctive relief necessary to allow Keryx to continue development of the licensed drug for the benefit of kidney patients in the United States, Japan and elsewhere around the world. See e.g., Seitzman v. Hudson River Assocs., 126 A.D.2d 211, 214, 513 N.Y.S.2d 148, 150 (1st Dep’t 1987) (“when the court balances the equities in deciding upon injunctive relief, it must consider the ‘enormous public interests involved.’”) (citations omitted); New York SMSA Ltd. P’Ship v. 225 5th, LLC, 8 Misc. 3d 1019(A), 1019(A), 803 N.Y.S.2d 19, 19 (Sup. Ct. N.Y. Co. 2005) (enjoining termination of phone company’s lease where it would result in lost revenues and “affect the provision of emergency wireless services to the public”); RxUSA Wholesale, Inc. v. Dep’t of Health and Human Servs., 467 F. Supp. 2d 285, 291-92 (E.D.N.Y. 2006) (granting a preliminary injunction that “benefits the public interest” by ensuring the integrity of medications on the market).

On the other hand, Panion will not be harmed by an injunction requiring it to act in accordance with the duties it expressly undertook in the License Agreement -- thereby preserving

the opportunity for Keryx (and Panion) to properly respond to the Notice from the Japanese patent office and permitting Keryx to continue development of the Product in accordance with the License Agreement. And Panion “will suffer minimally by virtue of the relatively short period of time that this relief covers. The injunction granted here will remain in effect only until a decision on the merits can be rendered[.]” Travellers Intern. AG v. Trans World Airlines, Inc., 684 F. Supp. 1206, 1217 (S.D.N.Y. 1988) (citation omitted). Finally, having raised its phony breach claims as a pretext for renegotiating the License Agreement to take account of Keryx’s lucrative Japanese Tobacco sublicense, while refusing in bad faith to comply with its obligations regarding patent prosecution in Japan and to cease interference with Keryx’s authorized development work, Panion is in no position to argue equities. See Virgin Enterprises Ltd. v. Nawab, 335 F.3d 141, 151 (2d Cir. 2003) (evidence of bad faith can “affect the court’s choice of remedy”; reversing denial of preliminary injunction); LeSportsac, Inc. v. K Mart Corp., 607 F. Supp. 183, 187 (E.D.N.Y. 1984) (McLaughlin, J.) (discounting defendant’s claims of hardship and granting preliminary injunction, where “Defendant ha[d] brought these hardships on itself”), aff’d, 754 F.2d 71 (2d Cir. 1985).

Accordingly, the balance of hardship tips decidedly in Keryx’s favor.

CONCLUSION

For all of the foregoing reasons, the Court should grant Keryx's motion for a preliminary injunction.

Dated: New York, New York
November 21, 2007

Respectfully submitted,

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